ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

March 17 2000

Dockets Management Branch **(HFA-305)**
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: **Docket No. 99N-4784**
Premarket Notification; Requirement for Redacted Version of Substantially Equivalent Premarket Notification

Dear Sir/Madam:

Advanced Sterilization Products offers the following comments on the above referenced proposed rule.

1. FDA's time estimate for compliance with this proposed rule are severely understated. It has been our experience, based upon a recent request to redact 10 submissions, that it has taken us an average of 6.5 hours to redact each of our requested Premarket Notifications.
2. Proposed section 807.95(f)(1) starts "Not later than 30 days after the date of the FDA order issued ...". This is not a sufficient time to allow submitters to properly redact and deliver to FDA the required information. Given our time experience (comment 1 above) of 6.5 hours each, it would be more reasonable to allow submitters 60 days for compliance. This 30 day rule is also more burdensome on submitters located some distance from the Washington D.C. area in that we often do not receive the official copy of the order until 7 or more days after the issuance date.
3. It is unclear as to how FDA will handle a FOIA request for the entire Premarket Notification. Specifically, the entire file contains reviewer notes and memos which often contain confidential information. Under present policy, FDA sends a copy of the entire file to the submitter for redaction. Will submitters continue to have the opportunity to properly protect their confidential information contained in the FDA files but not part of the information that the submitter has directly supplied? We suggest that FDA add a section to the rule to address this situation based upon current FDA practice.

Thank you for the opportunity to comment of this proposed rule and for your consideration.

Sincerely,

Kevin Corrigan
Director, Regulatory Affairs

99N-4784

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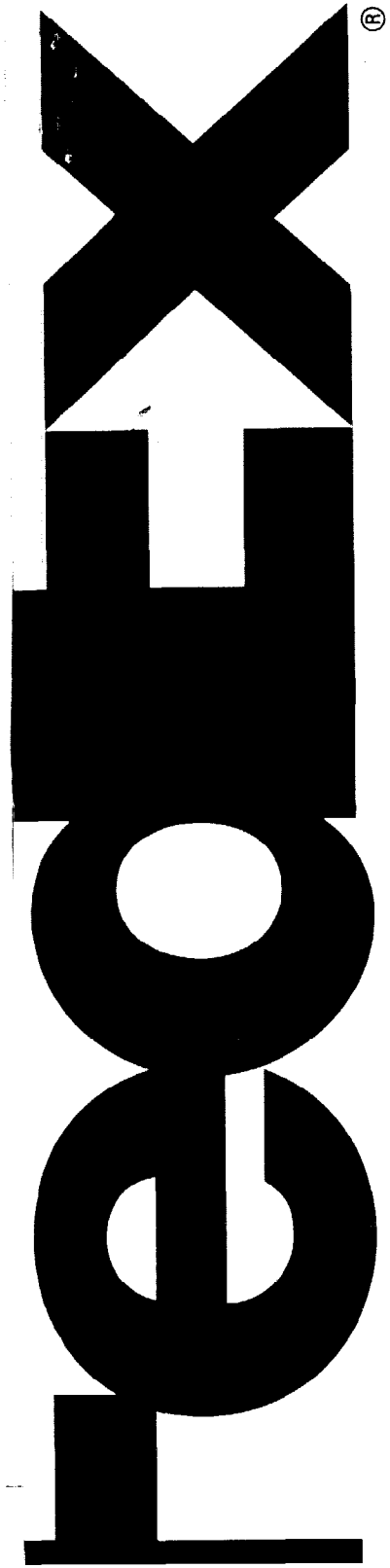

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